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Dated: April 23, 2003 Signature: (Monica L. Thomas)

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#10, Doc 5/2/03

Docket No.: HO-P02102US2
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Patent Application of:
Suzanne Fuqua, et al

Application No.: 10/052,092

Group Art Unit: 1632

Filed: January 18, 2002

Examiner: Bertoglio, Valarie

For: METHODS AND COMPOSITIONS IN BREAST CANCER DIAGNOSIS AND THERAPEUTICS

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, DC 20231

Dear Sir:

This is in response to the restriction requirement set forth in the Office Action mailed March 26, 2003.

The Examiner has required restriction between the following Groups:

Group I: Claim 1, drawn to a nucleic acid with an A908G mutation;

Group II: Claim 2, drawn to a polypeptide with a K303R substitution;

Group III: Claims 3-10, 12-14, 16-20, and 22, drawn to a method of detecting breast cancer using a nucleic acid assay and a kit comprising a nucleic acid primer for carrying out said method;

Group IV: Claims 3-9, 11-13, 15, 16-19, 21, and 24, drawn to a method of detecting breast cancer using immunoassay to detect an A908G mutation in an estrogen receptor alpha nucleic acid and a monoclonal antibody designed to bind an estrogen receptor alpha nucleic acid comprising an A908G mutation;

Group V: Claim 23, drawn to a monoclonal antibody that binds an acetylated estrogen receptor alpha polypeptide;

Group VI: Claims 25-32, drawn to a method of in vivo gene therapy to correct a G

mutation at nucleotide 908 of the estrogen receptor alpha nucleic acid sequence;

Group VII: Claims 33 and 34, drawn to a method of in vivo protein therapy to prevent breast cancer comprising administering a polypeptide comprising an estrogen receptor alpha sequence comprising a lysine residue at amino acid 303;

Group VIII: Claim 35, drawn to a method of identifying a modulator of a mutant estrogen receptor alpha K303R polypeptide in vitro by admixing the candidate modulator with a compound or cell;

Group IX: Claim 35, drawn to a method of identifying a modulator of a mutant estrogen receptor alpha K303R polypeptide in vivo;

Group X: Claims 36-44, drawn to a method of identifying a modulator of a mutant estrogen receptor alpha K303R polypeptide in vitro using recombinant cells comprising a vector encoding mutant estrogen receptor alpha K303R polypeptide and a vector comprising an estrogen-responsive regulatory element operably linked to a repoter polynucleotide;

Group XI: Claims 45 and 53, drawn to a method of treating breast cancer using an antagonist of a mutant estrogen receptor alpha K303R polypeptide;

Group XII: Claims 46-52, drawn to an in vitro method of identifying a polypeptide that interacts with an estrogen receptor alpha K303R polypeptide comprising introducing into a cell a vector comprising a chimeric estrogen receptor alpha K303R polypeptide and a DNA binding domain and a vector comprising a polynucleotide encoding a chimeric comprising a candidate polypeptide and a DNA activation domain;

Group XIII: Claims 54-56, drawn to an in vitro method of identifying a polypeptide that interacts with an estrogen receptor alpha K303R polypeptide comprising obtaining an affinity tagged estrogen receptor alpha K303R polypeptide, introducing said polypeptide to a plurality of bacteriophage that produce polypeptides and determining binding;

Group XIV: Claims 57-59, drawn to an in vivo method of identifying a compound for treatment of breast cancer;

Group XV: Claims 60-61, drawn to a compound having therapeutic activity for the treatment of breast cancer; and

Group XVI: Claims 62-63, drawn to a transgenic mouse comprising an estrogen receptor alpha having an A908G mutation.

Applicant hereby provisionally elects without traverse and without prejudice and acquiescence Group III having claims 3-10, 12-14, 16-20, and 22 for continued examination. Applicants reserve the right to pursue non-elected claims in other prosecution.

The Examiner furthermore set forth allegedly patentably distinct species for the claimed invention, namely Group A-G and Group H-X, and requested Applicants to elect a single disclosed species from each of these groups. Applicants contacted the Examiner in a telephonic interview of April 17, 2003 and requested clarification of these instructions. The Examiner clarified that it was not necessary to elect a species from a species Group if the claims were not directed to that element. Applicants thank the Examiner for her time and consideration.

Pursuant to the Examiner's requirement, Applicants elect SEQ ID NO:15 as a species for prosecution on the merits pursuant to the claims of Group III.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02102US2 from which the undersigned is authorized to draw.

Dated: 04/23/03

Respectfully submitted,

By

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TRANSMITTAL FORM

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Total Number of Pages in This Submission	4

Application Number	10/052,092
Filing Date	January 18, 2002
First Named Inventor	Suzanne Fuqua
Group Art Unit	1632
Examiner Name	V. Bertoglio
Attorney Docket Number	HO-P02102US2

ENCLOSURES (*check all that apply*)

- [ ] Fee Transmittal Form
  - [ ] Fee Attached
- [x] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Assignment Papers *(for an Application)*
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) *(please identify below)*

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Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm *or* Individual Name	FULBRIGHT & JAWORSKI L.L.P. Melissa W. Acosta
Signature	
Date	April 23, 2003

Transmittal

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